SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Multi-Parameter Mobile CareGuide™ 3100 Oximeter, with Tablet

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
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Email:	Babs.Soller@reflectancemedical.com
Date Prepared:	12/19/2013

Device Name

Trade name of New Device:	Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number:	3100
510(k) Holder/Submitter:	Reflectance Medical, Inc. (RMI)
510(k) Number:	N/A
Product codes:	21 CFR § 870.2700, 21 CFR 868.1170
Classification Panel:	Cardiovascular

Predicate Devices

Predicate Device #1:	Mobile CareGuide
Trade Name of Device:	Multi-Parameter Mobile CareGuide Oximeter
Model #:	3100
510(k) Holder/Submitter:	Reflectance Medical Inc.
510(k) Numbers:	K130079, CareGuide 3100
Product codes:	MUD, 21 CFR 870.2700, Cardiovascular CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2:	CareGuide
Trade Name of Device:	CareGuide Oximeter
Model #:	1100
510(k) Holder/Submitter:	Reflectance Medical Inc.
510(k) Numbers:	K113656, CareGuide 1100
Product code:	MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO_2) and muscle pH (pHm) and displays those parameters as real-time values and historical trends on a tablet device.

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor, disposable pad and display tablet
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO_2 and pHm from collected spectra and communicates the current SmO_2 and pHm results to an Android tablet with display software through a proprietary protocol. The Android tablet (qualified models Acer A500 and Asus Google Nexus 7) contains 3rd party software that locks down the tablet so that only the CareGuide software may run and no other application or operating software can be modified. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the Android tablet. The sensor is identical to the predicate (K130079) Multi-parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same disposable element as the Multi-Parameter Mobile CareGuide 3100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide 3100 device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The device's pHm feature has been already cleared under classification regulation 21 C.F.R § 868.1170, Anesthesiology. This 510(k) is seeking clearance for use of the CareGuide 3100 with a dedicated Android Display device.

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides diagnostic output.

The Multi-Parameter CareGuide 3100 with Tablet has the same technological characteristics as the previously cleared RMI devices, the CareGuide 1100 (K113656) and the Multi-Parameter Mobile CareGuide 2100 (K130079).

- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO2 and pHm is used in both devices.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in reusable components. Both devices use the exact same sensor hardware: main sensor CPU board, battery, optical board (light sources, spectrometer and microprocessor), USB interfaces, plastic housing and cables.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Table is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in disposable components. Both devices use the exact same disposable sheath ("Ray") and disposable sensor check device ("Cradle").

- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the identical underlying LED light source as the CareGuide predicates, with the exact same range of wavelength (700-900 nm).
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet and the predicated CareGuide 1100 Oximeter are equivalent. The CareGuide 1100 System includes a Monitor display while the CareGuide 3100 {subject of this 510(k)} includes a dedicated Android display. Both displays are functionally equivalent. Both CareGuide 1100 and 3110 displays are tools that interface with the CareGuide oximeter and display real-time parameters and historical trends per their cleared indications for use.
- The predicate Multi-Parameter Mobile CareGuide 3100 Oximeter is compatible with any USB-connected display device that supports the specified communications protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)} now includes such a USB-connected display device (i.e. dedicated Android tablet), supporting that specified communications protocol.

Summary of Safety and Effectiveness Data

Bench testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is safe and effective, meeting all relevant consensuses and FDA recognized standards. The bench and software test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet meets the expected performance requirements for an Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is therefore equivalent to the predicates by indications for use and device features and functionality.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Reflectance Medical, Inc.
Babs Soller
Chief Executive Officer
116 Flanders Road,
Suite 1000
Westborough, MA 01581 US

Re: K133923
Trade/Device Name: Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet
Regulation Number: 21 CFR 870.8700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 7, 2014
Received: March 13, 2014

Dear Dr. Soller,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

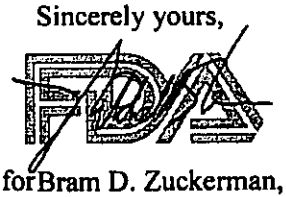
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K133923

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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